K061131

FEB 8 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Orthocon, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 167 Stone Hill Road
Colts Neck, NJ 07722

Telephone: (732) 683 - 9304
Fax: (732) 683 - 9476

Date Prepared February 22, 2006

General Device Information

Product Name: DBX-H™ Hemostatic Demineralized Bone Matrix Putty

Classification: "Bone Void Filler" and "Bone Wax",
21 CFR 888.3045 - Product codes: MBP and MTJ
Class II

Predicate Devices

DBX® Demineralized Bone Matrix Putty
Musculoskeletal Transplant Foundation
510(k) K040262

Grafton DBM
Osteotech, Inc.
510(k) K051195

Description

DBX-H Hemostatic Demineralized Bone Matrix Putty is processed human bone that has been demineralized and combined with an absorbable carrier that is biocompatible and biodegradable. The combination of demineralized bone and the absorbable carrier results in a putty-like consistency for ease and flexibility of use during surgical application. The carrier material is a mixture of calcium stearate (a wax-like material) and triethyl citrate (a dispersing agent). DBX-H Putty is virtually odorless, off-white in color and can be spread easily with minimal adhesion to surgical gloves.

DBX-H is intended for use as a filler for voids or gaps that are not intrinsic to the stability of the bony structure. When applied manually to surgically incised or traumatically broken bone, DBX-H Hemostatic Demineralized Bone Matrix Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade). The putty will be dispersed and absorbed through exposure to body temperature, body fluids and cellular transport within a period of 90 days.

Intended Use (Indications)

DBX-H™ Hemostatic Demineralized Bone Matrix Putty is indicated for use for filling voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the extremities and pelvis.

DBX-H™ can help control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used for treatment of surgically created osseous defects and in osseous defects resulting from traumatic injury.

Substantial Equivalence

This submission supports the position that DBX-H™ Hemostatic Demineralized Bone Matrix Putty is substantially equivalent to a number of pre-enactment and previously cleared devices, including:

DBX® Demineralized Bone Matrix Putty - Musculoskeletal Transplant Foundation [510(k) K040262]

Grafton DBM - Osteotech, Inc. [510(k) K051195]

The 510(k) Notice contains summaries of physical test results, functionality (efficacy testing) results and biocompatibility testing.

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use.

Conclusions

Orthocon, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the DBX-H™ Hemostatic Demineralized Bone Matrix Putty. The materials from which the Orthocon device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthocon, Inc.
% Mr. Howard Schrayer
Regulatory Affairs Consultant
167 Stone Hill Rd.
Colts Neck, New Jersey 07722

FEB 8 2007

Re: K061131
Trade Name: DBX-H Hemostatic Demineralized Bone Matrix Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Filler, Bone Void, Demineralized Bone Matrix
Regulatory Class: Class II
Product Code: MBP, MTJ
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

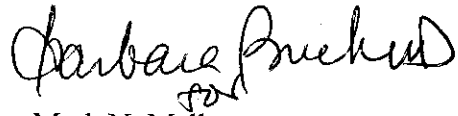
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120.Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: DBX-H™ Hemostatic Demineralized Bone Matrix Putty

Indications For Use:

DBX-H™ Hemostatic Demineralized Bone Matrix Putty is indicated for use for filling voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the extremities and pelvis.

DBX-H™ can help control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used for treatment of surgically created osseous defects and in osseous defects resulting from traumatic injury.

Prescription Use ____X____ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061131